K131745

510(k) Summary
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Date Prepared: 12-Jun-2013

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SEP 17 2013

Official Contact: Thomas Vassallo
Executive Vice president

Proprietary or Trade Name: Blom-Singer® Septal Perforation Prosthesis

Common/Usual Name: Nasal septal button

Classification Name: LFB – unclassified
Nasal septal button

Predicate Devices: K013686 – Silmed Nasal Septal Button
K810738 – Xomed-Treace – Goode-Magne nasal splint

Device Description:
The Blom-Singer® Septal Perforation Prosthesis is a bi-flanged elastomeric device, each prosthesis are comprised of two (2) pieces which are attached to one another using a set of 2 enclosed magnets at the center of the flanges. The center post is either an oval or circular silicone stem that will fill most of the nasal septal perforation. The overlapping thin section or flange will extend beyond perforation to help with the closure of the perforation and the retention of the device.

The flanges will be offered is various sizes and shapes to accommodate the individual's septal shape. In addition, the clinician may trim the flanges to fit.

The device is intended to be used up to 29 days.

Indications for Use:
The Blom-Singer® Septal Perforation Prosthesis is indicated for use for non-surgical closure of nasal septum perforations.

Patient Population:
The patient population is people who have a nasal septal perforation.

Environment of Use:
The product will be placed in an outpatient or clinical setting by a qualified and trained medical professional.

The patient may use the product in a hospital, clinical setting, or at home under the instructions of a qualified medical professional.

Contraindications:

- Septal deformities are relative contraindications for prosthesis placement, as the flange on the convex side of the deformity may increase nasal obstruction.
- Women who are pregnant should consult their doctor before using a medical device containing a magnet
- People who have pace makers, defibrillators, diabetic pumps or other electro-medical equipment.
- Should not be in situ during MRI examination (Magnetic resonance imaging)
- Should not be in situ during radiation therapy

Substantial Equivalence Discussion

Table 1 compares the key features of the proposed Blom-Singer® Septal Perforation Prosthesis with the identified predicate and it demonstrates that the proposed device can be found to be substantially equivalent.

In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K013686 – Silmed Nasal Septal Button.
Discussion – Each device is indicated for use for non-surgical closure of nasal septum perforations.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate – K013686 – Silmed Nasal Septal Button.

The technology of using magnets for "attaching" 2 components is equivalent to the predicate – K810738 – Xomed-Treace – Goode-Magne nasal splint.
Discussion – The design incorporates 2 thin, flat flanges of varying shapes which are connected in the center.

Environment of Use –
The environments of use are identical to predicate – K013686 – Silmed Nasal Septal Button.
Discussion – The environments of use are identical to the predicate – K013686 – Silmed Nasal Septal Button.

Patient Population –
The patient population of individuals which have a perforated nasal septum is equivalent to the predicate – K013686 – Silmed Nasal Septal Button.

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Discussion – The patient populations are equivalent to the predicate – K013686 – Silmed Nasal Septal Button.

Non-Clinical Testing Summary –

We performed a number of bench tests which demonstrated that the proposed device would meet the requirements for the intended and environment of use.

These tests included

- Mechanical strength of magnets
- Real-time aging
- Environmental and mechanical testing
- Cleaning degradation

Discussion – All testing demonstrated that the proposed device meets its performance requirements and is substantially equivalent to the predicate device.

Materials –
We have provided letters allowing FDA access to the Master Device File.

The materials in patient contact are considered per G95-1 as:

- Surface Communicating (direct)
- Mucosal contact
- Prolonged duration of use (> 24 hours < 30 days)

Based upon G95-1 the following tests are required if a material certification cannot be provided.

- Cytotoxicity
- Sensitization
- Intracutaneous / Irritation

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Attribute	Proposed Blom-Singer® Septal Perforation Prosthesis	Predicate Silmed – Nasal Septum Button K013696
Indications for Use	The Blom-Singer® Septal Perforation Prosthesis is indicated for use for non-surgical closure of nasal septum perforations. Environment of use – hospital, sub-acute, physician office settings.	Indicated for non-surgical closure of nasal septum perforations. Environment of use – hospital, sub-acute, physician office settings.
Environments of use	The product will be placed in an outpatient or clinical setting by a qualified and trained medical professional. The patient may use the product in a hospital or clinical setting, or at home under the instructions of a qualified medical professional.	The product will be placed in an outpatient or clinical setting by a qualified and trained medical professional. The patient may use the product in a hospital or clinical setting, or at home under the instructions of a qualified medical professional.
Prescriptive	Yes	Yes
Patient population	The patient population is people who have a nasal septal perforation.	The patient population is people who have a nasal septal perforation.
Single patient use	Yes, up to 29 days	Yes
Basic components	Thin flat flanges of various sizes and shapes held together via 2 magnets	Thin, flat circular flanges of various sizes centrally connected by a post
Technology of attaching Flanges	Magnets	Center mechanical post Predicate which uses magnets to hold together 2 nasal splint K810738 – Xomed-Treace Goode-Magne Splint Plus
Sizes	Various sizes and shapes	Various sizes and shapes
Materials	Silicone Parylene C Rare earth magnets (sealed and not in patient contact)	Silicone Rare earth magnets (sealed and not in patient contact)
Performance testing	Pull test for strength of magnets	
Testing	Mechanical Real-time aging Cleaning degradation	

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

September 17, 2013

Helix Medical, LLC
c/o Mr. Paul E. Dryden
Regulatory Consultant
1110 Mark Ave.
Carpinteria, CA 93013

Re: K131745/S001
Trade/Device Name: Bloom-singer Septal Perforation Prosthesis
Regulation Number: Unclassified
Regulatory Class: Unclassified
Product Code: LFB
Dated: August 11, 2013
Received: August 13, 2013

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for: Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K131745 (To be assigned)

Indications for Use:

The Blom-Singer® Septal Perforation Prosthesis is indicated for the non-surgical closure of nasal septal perforations.

Environment of use – hospital, sub-acute, physician office settings.

Prescription Use XX or **Over-the-counter use __**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vasant G. Malshet

Digitally signed by Vasant G. Malshet
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Vasant G. Malshet, 0.9.2342.19200300.100.1.1=13001087851
Date: 2013.09.17 14:04:00 -04'00'